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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,779	05/29/2007	Petra Allef	58763.000032	4040
21967 7590 10/08/2008 HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109				
EXAMINER				
HOBBS, LISA JOE				
ART UNIT		PAPER NUMBER		
1657				
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10/08/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/593,779

**Applicant(s)**

ALLEF ET AL.

**Examiner**

Lisa J. Hobbs

**Art Unit**

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/55/08)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Claim Status***

Claims 31-65 are active in the case. Claims 1-30 have been cancelled by preliminary amendment during the PCT examination process. Claims 31-65 are under examination; no claims are withdrawn as drawn to a non-elected invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-47, 57-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 31 and 57 recite that the method and kit detect directly "an effect" caused by a population of organisms. It is unclear what the word "effect" is meant to encompass; the metes and bounds of these claims, and also the instant dependent claims, cannot be determined. For the purposes of this examination, the examiner has interpreted the claim to recite "a method to detect directly an enzymatic activity" of a group of organisms. Since the independent claims all recite methods of determining enzymatic activity and no other "effect".

Claims 48-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 48, 49, and 52 recite methods wherein step a) of each comprises that a particular enzymatic activity is "responsible for said effect". However, there is no effect claimed in the preambles to the claims and the claims are not dependent from independent claims 31 or 57 where an "effect" is recited. It is unclear what applicant intends to claim with the recitation of "said effect" thus, for the purposes of the instant examination, the examiner has interpreted the methods to recite determination of enzymatic activity of a population of organisms "of interest".

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheiness et al. (US 5,700,636 A and US 5,776,694 A), Chen et al. (US 5,854,011 A and US 6,984,499 B2, filed 02 October 1997), Laine et al. (US 6,184,027 A), Loesche (US 5,116,735 A), and Godsey et al. (US 5,888,760 A), in view of Roger-Dalbert (US 2004/0048326 A1), Reymond et al. (US 2003/00199017 A1), and James et al. (US 2002/0031795 A1).

Sheiness et al. teach methods and kits for selectively detecting a prokaryotic microorganism and a eukaryotic microorganism in a single complex biological sample wherein the cells of such microorganisms are lysed by combining the sample with a lysis solution"; the lysis and detection is performed without culturing the organisms (abstract). Chen et al. ('011) teach "A composition and method for detecting the presence or amount of yeasts and molds in a test sample is presented. The composition contains a substrate and an inhibitor for an aminopeptidase. The substrate has a signal moiety capable of providing a detectable signal when cleaved by an aminopeptidase in yeasts or molds. The aminopeptidase inhibitor serves to reduce the endogenous aminopeptidase activity in the test sample. The method to detect yeasts or molds in a sample includes inoculating a test sample with the disclosed composition, incubating the sample and observing any detectable signal that indicates the presence of yeasts or molds" (abstract). As well, Chen et al. ('499) teach "[a] method of detecting the presence or urinary

pathogens in a biological sample and of simultaneously determining the susceptibility of the urinary pathogens to antimicrobial agents...whereby metabolism of a signal generating substrate and production of a detectable signal...indicates the presence of microbial organisms in the sample” and also indicates a resistance to the antimicrobial compound being tested (claim 1).

Laine et al. teach “catalytically inactive murein binding enzyme diagnostic reagents and methods and kits for detecting eubacteria and fungus in biological samples” (abstract). Loesche teaches “a colorimetric assay for diagnosis of periodontal disease is carried out by using a chromogenic test substance which is hydrolyzed by trypsin-like enzymes produced by periodontopathogenic bacteria in a sample specimen of subgingival plaque to release a chromophore. The presence of periodontal disease is thus indicated by a color change” (abstract). Godsey et al. teach “a universal test systems and methods of use thereof for identifying a microorganism among at least two groups of widely divergent microorganisms. The universal test system comprises a predetermined combination of non-redundant biochemical tests comprising a substrate for at least one enzyme wherein the substrate, if acted on by the enzyme results in formation of a detectable product. Detectable products from the combination of biochemical tests are then used to identify the microorganism” (abstract).

Roger-Dalbert teaches “a method and a medium for microbiological analysis by biochemical means involving chromogenic or fluorogenic substrates that react with enzymes (esterases) specific for the target strains...to improve the sensitivity, initial translucence, stability and ease of use of such detection/identification media. For this purpose the medium according to the invention is characterized in that it is in a stable, ready-to-use liquid or gel form and in that it contains a solubilizer and stabilizer selected from fatty acid sorbitan esters, bile salts and

mixtures thereof, as well as a selective activator selected from alkylsulfate salts, for example the sodium salts. The medium can comprise a solvent, for example dimethyl sulfoxide” (abstract).

Reymond et al. use lipases or esterases to “release[e] a product that comprises, a volatile molecule or an active substance or else a specific product. The invention also relates to a method for detecting the released product as well as its applications, in particular for detecting catalytic or enzymatic activities”, such as detection by odor (abstract and [0024]). James et al. teach nitrocoumarin substrates for “detecting the presence or absence of at least one microorganism. The invention also concerns the use of a compound in a detection and/or diagnostic test. The said invention further concerns a method for detecting nitroaryl reductase activity in a bacteria culture medium. Finally, the invention concerns the use of such a compound, methods for isolating and detecting microorganisms or a group of microorganisms in a sample likely to contain them, and various applications thereof” (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Sheiness et al., Chen et al., Laine et al., Loesche, and Godsey et al., with those other teachings in the acknowledged prior art with the teachings of Roger-Dalbert, Reymond et al., and James et al. to achieve the instant invention as recited. Each of the methods and kits recited teach the concept of determining the presence of groups of organisms using various screening methods, including susceptibility or resistance to antimicrobial compounds. Each of the substrate teachings discloses that substrates for specific enzymes which are employed to achieve a specific purpose, such as colorimetric change, fluorescence, or generation of volatile compounds are known to those of skill in the art and are known to be employed in organism detection methods. One would have a reasonable

expectation of success in combining these teachings since organism assays are well described and the instant patents disclose that the test conditions may be undertaken with various groups of unknown organisms in a sample. One would be motivated to combine the teachings to achieve rapid, reliable, easy to interpret tests for organisms of interest to protect the human population from pathogens, for example, anthrax as taught by Laine (col. 16, lines 57).

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Monday to Friday, 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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/Lisa J. Hobbs/  
Primary Examiner  
Art Unit 1657

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